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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): FXH1006USC1

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Application Number	Filed
10/625,145	July 22, 2003

First Named Inventor: Stephen W. Boyd

Art Unit	Examiner
3731	Victor X. Nguyen

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 33,984.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

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December 2, 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

REMARKS

In the Final Office Action dated August 3, 2010 the Examiner rejected claim 16 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,156,046 to Passafaro et al. (Passafaro) and rejected claim 28 under 35 U.S.C. § 103(a) as being unpatentable over Passafaro in view of U.S Patent No. 5,776,141 to Klein et al. (Klein). Applicant requests a pre-appeal brief review of these rejections based upon the following clear errors:

(1) The Examiner's determination that Passafaro discloses all of the limitations of claim 16 is erroneous since the Examiner improperly combined selected elements from the device disclosed by Passafaro with elements of a second device.

(2) The Examiner's determination that Passafaro discloses all of the limitations of claim 16 is erroneous since the Examiner failed to properly consider all of the limitations of claim 16.

(3) The Examiner's determination that claim 28 is unpatentable over Passafaro in view of Klein is erroneous since the Examiner has failed to provide any reasoned explanation to support the combination suggested by the Examiner.

Applicant will discuss each of these errors separately below.

(1) The Examiner's determination that Passafaro discloses all of the limitations of claim 16 is erroneous since the Examiner improperly combined selected elements from the device disclosed by Passafaro with elements of a second device.

Claim 16 is directed to a device for removing material from a vessel wall at a vascular site and comprises both an expandable cage and a material removing element positioned within a cavity defined by an inner surface of the cage. The Examiner states that Passafaro discloses in FIGS. 10I to 10M a stent having the features of the cage recited in claim 16 and a material removal element 54 positioned within the cage cavity. Therefore, the Examiner concludes that Passafaro anticipates claim 16. Applicant respectfully points out, however, that the stent forms no part of the system disclosed by Passafaro.

Specifically, Passafaro discloses a material removal system 30 that includes a catheter 32 which has a flexible elongate catheter body 34 having a proximal end 36 and a distal end 38, and defining at least one lumen 50 extending longitudinally therethrough. The catheter is coupled to a hand-held device 42 and a collection reservoir 44. The hand-held device includes a motor for

rotating a removal mechanism 54 provided at a distal end 38 of the catheter 32 to extract occluding material. (Passafaro, col. 8, lines 15 to 25). The system disclosed by Passafaro is for removing stenotic material from blood vessels including vessels in which a stent has been previously implanted. (Passafaro, col. 7, lines 18 to 21 and col. 20, lines 1 to 3 and lines 7 to 13). In other words, the system which is disclosed by Passafaro does not include the stent which is described as having been previously implanted. The stent merely forms a part of the environment in which the device may be used.

In order to anticipate under 35 U.S.C. § 102 a prior art reference must not only disclose all of the elements of the claim within the four corners of the document but must also disclose those elements "arranged as in the claim". *Net Moneyin v. Versign*, 545 F. 3d 1359, 1369 (Fed. Cir. 2008). In making this rejection the Examiner has combined an element of the removal device disclosed by Passafaro with an element that Passafaro clearly discloses as being an element (the stent) of a different device which was previously implanted in a different and prior procedure. Clearly, Passafaro does not disclose the elements of claim 16, as arranged in the claim, which requires a single device that includes both a cage and a material removal element. Therefore, Passafaro does not anticipate claim 16 and Applicant respectfully requests that the rejection be withdrawn.

(2) The Examiner's determination that Passafaro discloses all of the limitations of claim 16 is erroneous since the Examiner failed to properly consider all of the limitations of claim 16.

Claim 16 includes at least two features that have not been properly considered by the Examiner. Specifically, claim 16 requires that the cage be (1) "moveable from a collapsed position to an expanded position", and that the cage be (2) "releasable so that the cage may be left within the patient". As noted above, the Examiner considers the stent, which was previously implanted in a separate procedure unrelated to the procedure disclosed by Passafaro using a separate device unrelated to the device disclosed by Passafaro, as being the cage. Further, the Examiner believes that the device which anticipates claim 16 is shown in FIGS. 10I to 10M. In other words, the device identified by the Examiner includes the previously implanted stent S and the material removing element 54. At the time of the procedure described by Passafaro, which is shown in the figures identified by the Examiner, the previously implanted stent has already become occluded with occluding material OM.

Although the stent may have been movable from a collapsed position to an expanded position when it was originally implanted in the previous procedure and although it may have been releasable from the separate device used to implant it, the stent is neither expandable nor releasable as shown in FIGS. 10I to 10M in connection with the use of the material removal system disclosed by Passafaro. In other words, by the time the stent becomes associated in any manner with the material removal device disclosed by Passafaro it is no longer "movable from a collapsed position to an expanded position", it is merely a previously expanded stent that comprises a part of the work environment for Passafaro's material removal device. Further, the stent is not "releasable" from the material removal device disclosed by Passafaro, having already been released, presumably from a stent delivery catheter during the previous procedure. Additionally, the feature of being "releasable" implies that there is some connection to the device which can be released. Passafaro discloses no connection or relationship between the material removal system and the stent other than that the material removal device can be used to remove occluding material from an occluded stent. The stent is in the vessel before, during, and after use of the material removal system described by Passafaro and is not "releasable" from any part or element of that system. Therefore, Passafaro does not anticipate claim 16 for these additional reasons and Applicant requests that the rejection be withdrawn.

(3) The Examiner's determination that claim 28 is unpatentable over Passafaro in view of Klein is erroneous since the Examiner has failed to provide any reasoned explanation to support the combination suggested by the Examiner.

Claim 28 is directed to a device for removing material from a vessel wall at a vascular site and comprises a sheath, an expandable and releasable cage and a material removing element positioned within a cavity defined by an inner surface of the cage. The sheath is retractable relative to the cage to expose the cage and permit the cage to expand. As discussed above, Passafaro does not disclose a device which includes a releasable and expandable cage and a material removal element. In the Final Office Action the Examiner acknowledges that Passafaro fails to disclose an expandable cage being contained within a sheath and the sheath being retractable relative to the cage to expose or expand the cage. However, on page 4, lines 13 to 15 the Examiner cites Klein as teaching "an expandable cage S being contained within a sheath 70 and the sheath 70 is retractable relative to the cage to expose or expand the cage". The Examiner concludes that "it would have been obvious to one having ordinary skill in the art at the time the

invention was made to modify the device of Passafaro with an expandable cage being contained within a sheath and the sheath is retractable relative to the cage to expose or expand the cage in order to deliver a proper stent to intraluminal target sites." (Emphasis supplied).

Applicant submits that a person of skill in the art would not, in view of the combined teaching of Passafaro and Klein, modify the material removal system disclosed in Passafaro to include a stent. The system disclosed by Passafaro is intended to be used to remove occluding material from a body vessel, including occluding material from within a stent which was previously implanted in the vessel and which, over a period of time, has become occluded. The stent, however, plays no part in the material removal process. As a matter of fact, the stent complicates the process. As stated by Passafaro, "[t]reatment of an occluded stent faces all the difficulties discussed above with respect to treatment of initial occlusions and is further complicated by the need to avoid damaging the stent during the removal of the hyperplasia occluding material." (Passafaro, col. 2, lines 58 to 63). Therefore, a person of skill in the art would have no reason to intentionally incorporate a stent into the system disclosed by Passafaro (or a stent and sheath as disclosed in Klein) since such modification would provide no functional advantage and would, in fact, further complicate use of the device. Additionally, a person of skill in the art would understand that a stent is deployed in a vessel for the purpose of opening and maintaining the patency of the vessel. The person of skill in the art also understands that although some stents will eventually become occluded with occluding material, that result is undesirable and does not occur until after the passage of considerable time. Therefore, the person of skill in the art would have no reason to combine a stent delivery catheter with a device to remove occluding material from an implanted stent since the person of skill in the art understands that a stent becomes occluded, if at all, only after the passage of time so there would be no reason to include a material removal device at the time the stent is initially implanted.

Even if the person of skill in the art desired to treat a vessel using both the stent therapy of Klein and the material removal therapy of Passafaro those therapies would not be combined in the manner suggested by the Examiner. Passafaro makes it clear that the presence of a stent makes use of the material removal system more complicated. Therefore, if the person of skill in the art desired to use both forms of treatment the person of skill would first remove occluding material from the vessel with the Passafaro device and then deploy the stent. Although Applicant submits that neither Passafaro nor Klein teach the combination of such therapies in a

single treatment device, Applicant believes that such combination, even if made, would not result in a device having the features of claim 28. For at least these reasons Applicant believes claim 28 is allowable and request that the rejection be withdrawn.

Conclusion

The Examiner's rejections of claims 16 and 28 are erroneous and should be withdrawn for at least the reasons set forth above. The remaining pending claims are allowable for at least the same reasons. Applicant respectfully requests pre-appeal brief review of these issues.